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10/542,708	11/10/2005	Annie Borgne	BJS-1721-96	5777

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EXAMINER	
GIBBS, TERRA C	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/542,708	BORGNE ET AL.	
	Examiner	Art Unit	
	TERRA C. GIBBS	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 July 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *July 20, 2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Supplemental Non-Final Office Action

Withdrawal of Previous Office Action

The Office Action mailed August 28, 2008 is withdrawn in view of the supplemental non-final office action presented below.

In the previous Office Action mailed August 28, 2008, the Examiner inadvertently failed to acknowledge Applicant's Preliminary Amendment filed November 10, 2005, which amended claims 7-9 to be properly dependent on a previous claim. In this regard, claims 7-9 have been examined on the merits as detailed below.

This Office Action is a response to Applicant's Election filed May 16, 2008.

Claims 1-9 are pending in the instant application.

Election/Restrictions

Applicant's election of Group II, drawn to an inhibitory RNA having the sequence of SEQ ID NO:2 in the reply filed on May 16, 2008 is acknowledged. Because Applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election **without** traverse (MPEP § 818.03(a)).

SEQ ID NO:1 and SEQ ID NO:3 as recited in claim 3 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. As noted above, because Applicant

did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election **without** traverse.

The requirement is still deemed proper and is therefore made FINAL.

Accordingly, claims 1-9 and SEQ ID NO:2 have been examined on the merits.

Specification

Applicant's reference to priority in the first sentence of the specification is acknowledged.

It is noted that the instant specification at page 15 lists numerous non-patent literature. If Applicants wish to have these references considered by the Office, Applicants should include them in an information disclosure statement filed under 37 CFR § 1.97.

Drawings

The drawings filed on July 20, 2005 are acknowledged. The drawings are objected to because the description of the drawings indicates that such material may very well be critical to determining whether there exists adequate description and enablement of the instant invention. In brief, Figures 2A, 2B, 2C, 3A, and 3B are sufficiently poor enough that it is difficult to determine what is actually being described. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to

avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the Examiner, the Applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Nucleotide Sequence Disclosures

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. §1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §1.821-1.825 for the reason(s) set forth below or on the attached Notice To Comply with Requirements for Patent Applications Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures. The disclosure contains sequences which fall under the purview of 37 CFR 1.821 through 1.825 as requiring SEQ ID NOs., but

which are not so identified. For example, see page 11, lines 3-7. Applicant must fully comply with the sequence rules for any response to this action to be considered fully responsive.

Information Disclosure Statement

Applicant's information disclosure statement filed July 20, 2005 is acknowledged. The submission is in compliance with the provisions of 37 CFR §1.97. Accordingly, the Examiner has considered the information disclosure statement, and a signed copy is enclosed herewith.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-9 are indefinite because the terms "iRNA" and "ANT" are not clearly defined. Since abbreviations often have more than one meaning, it is suggested that inserting the full name of the respective RNA and translocation protein would overcome the instant rejection.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, and 4-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The claimed invention is drawn to an iRNA capable of selectively inhibiting the expression of an ANT isoform, characterized in that said iRNA is an RNA duplex, one of the strands being highly homologous to a fragment of the mRNA encoding said ANT isoform.

The invention encompasses iRNA capable of selectively inhibiting the expression of an ANT isoform that encode all forms of ANT, which includes sequences form other species, mutated sequences, polymorphic and allelic variants, splice variants, sequences that have an unspecified degree of identity (similarity, homology) and so forth. The specification teaches that human ANT exists in three isoforms, ANT1, ANT2, and ANT3 (SEQ ID NOs: 19, 20, and 21, respectively). WO 0185944 teaches SEQ ID NOs: 1, 2, and 3 which are 100% complementary to SEQ ID NOs: 19, 20, and 21, respectively, of Applicant's invention. There is no disclosure found in the specification that relates the structure of an iRNA capable of selectively inhibiting the expression of an ANT isoform. The claims are directed to encompass a broad range of iRNA capable

of selectively inhibiting the expression of *any* ANT isoform of highly variant structures (e.g. nucleic acid sequence), which have not been described in the specification and whose structure could not be envisioned by the skilled artisan based on the disclosure of the specification.

At the outset, it is noted that the rejected claims do not recite any sequence identifier relating to ANT isoform. This sequence is thus considered to be defined by its function (i.e. the activity of ANT) rather than by any one specific structure. Accordingly, the claims embrace iRNA capable of selectively inhibiting the expression of *any* ANT isoform, or any such molecule with analogous ANT activity, known or yet to be discovered, along with any isoform or allele present within this species, or any variant, polymorphic or otherwise, that is within reasonable similarity from these families of proteins that retain ANT activity.

To satisfy the written-description requirement, the specification must describe every element of the claimed invention in sufficient detail so that one of ordinary skill in the art would recognize that the inventor possessed the claimed invention at the time of filing. Thus, an applicant complies with the written-description requirement by describing the invention, with all its claimed limitations, and by using such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention. To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical, structure/function correlation,

methods of making the claimed product, and any combination thereof. The representative sample requirement may be satisfied by supplying structural or functional information, or a combination of both, such that one of skill in the art would be satisfied that applicants were in possession of the genus as claimed. Further, the size of the representative sample required is an inverse function of the unpredictability of the art.

See the January 5, 2001 (Vol. 66, No. 4, pages 1099-1111) Federal Register for the Guidelines for Examination of Patent Applications Under the 35 USC 112 ¶ 1, "Written Description" Requirement. These guidelines state: "[T]o satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that applicant was in possession of the claimed invention.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the

'written description' inquiry, whatever is now claimed." (see page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invention what is claimed." (See Vas-Cath at page 1116).

One cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 1481, 1483. In Fiddes, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

In order to synthesize the iRNA capable of selectively inhibiting the expression of an ANT isoform as claimed, one of skill would first need the sequence of the ANT. The specification teaches that ANT exists in three isoforms, ANT1, ANT2, and ANT3, however, the claims are directed to encompass a broad range of *any* ANT isoform, including sequences form other species, mutated sequences, polymorphic and allelic variants, splice variants, sequences that have an unspecified degree of identity (similarity, homology). Thus, one of skill in the art could not immediately envision the genus of iRNA capable of selectively inhibiting the expression of an ANT isoform based on the disclosure, particularly in the absence of any teaching by way of structure or reference to active domains or regions within ANT. The genus is not immediately envisioned because the genus of iRNA capable of selectively inhibiting the expression of an ANT isoform is considered to include not only the ANT1, ANT2, and ANT3 sequences taught in the instant specification and in the prior art, but also any such molecule with analogous ANT activity, known or yet to be discovered, along with any isoform or allele present within this species, or any variant, polymorphic or otherwise,

that is within reasonable similarity from these families of proteins that retain ANT activity. However, the distinguishing characteristics of the claimed genus are not considered to be described herein. Thus, because one of skill in the art could not envision any ANT sequence, other than those sequences taught in the instant specification and in the prior art, one of skill would not be convinced that applicants were in possession of any iRNA capable of selectively inhibiting the expression of an ANT isoform sequences that are heretofore undescribed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 2, and 4-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Faure-Vigny et al. (Molecular Carcinogenesis, 1996 Vol. 16:165-172, submitted and made of record in Applicant's information disclosure statement filed July

20, 2005) or WO 9410320, in view of Hammond et al. (Nature Genetics 2001, Vol. 2:110-119), Elbashir et al. (Methods, 2002 Vol. 26:199-213), and WO 0185944 A2.

Claim 1 is drawn to an iRNA capable of selectively inhibiting the expression of an ANT isoform, characterized in that said iRNA is an RNA duplex, one of the strands being highly homologous to a fragment of the mRNA encoding said ANT isoform. Claims 2 and 4-9 are dependent on claim 1 and include all the limitations of claim 1 with the further limitations wherein the iRNA is an siRNA of 18 to 25 nucleotides, more particularly, 21 nucleotides; wherein the iRNA is contained in a construct; wherein the construct is associated with a vector; wherein the vector is a vector for transferring nucleic acids, such as retrovirus, transposon, adenovirus, or plasmid; a pharmaceutical composition characterized in that it contains an effective amount of at least one iRNA as claimed in claim 1 in combination with a pharmaceutically acceptable vehicle; the pharmaceutical composition of claim 1 characterized in that it is in injectable form, or in a form that can be administered orally, parenterally, rectally, or topically; and the iRNA of claim 1 characterized in that it has the ability to regulate mitochondrial membrane permeabilization and cell death of apoptotic, necrotic, and autophagic type and related mechanisms.

It is noted that some of the claims recite an intended use. For example, claim 9 recites that the iRNA is characterized in that is has the ability to regulate mitochondrial membrane permeabilization and cell death of apoptotic, necrotic, and autophagic type and related mechanisms. Applicant is reminded that the recitation of the intended use of the claimed invention must result in a structural difference between the claimed

invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the functionality of the claim(s).

Determining the scope and contents of the prior art

Faure-Vigny et al. teach the desire to design and use antisense oligonucleotides to inhibit ANT2 expression for the purpose of cancer therapy (see Abstract and page 171, last paragraph). It is noted that since the antisense oligonucleotides are used for the purpose of cancer therapy, one of ordinary skill in the art would believe them to comprise pharmaceutical compositions.

WO 9410320 teaches the desire to design and use antisense RNA targeted to ANT, wherein the ANT antisense comprises a binary vector (see Abstract, Example VII at page 22, and Figure 5, for example).

Ascertaining the differences between the prior art and the claims at issue

Neither Faure-Vigny et al. nor WO 9410320 teach an iRNA capable of selectively inhibiting the expression of an ANT isoform, characterized in that said iRNA is an RNA duplex.

Hammond et al. teach that antisense and RNA interference are two methods of silencing expression of a gene and that RNA interference possesses characteristics that make it superior to antisense. For example, on page 110, first column, Hammond teaches that antisense methods are straightforward but suffer from "questionable specificity and incomplete efficacy". RNA interference on the other hand, "has been shown in diverse organisms to inhibit gene expression in a sequence-specific manner"

(same page and column) and requires only a few molecules of dsRNA per cell to silence expression. Hammond also teaches that the RNA interference phenomenon in animals was discovered by researchers who were using antisense techniques and found that the use of double stranded instead of single-stranded RNAs reduced gene expression tenfold more efficiently (see paragraph bridging pages 110-111).

Elbashir et al. teach that RNA interference is mediated efficiently by synthetic RNAs that are 21-22 nucleotides in length and name these short duplexes "short interfering RNAs" (siRNAs) (see Abstract). Elbashir et al. teach the design of siRNA duplexes for interfering with the expression of a specific gene in which the target sequence is known (see page 200, second column and 2.1 Protocol). Elbashir et al. teach that siRNA comprises a sense RNA strand and an antisense RNA strand, wherein the sense and the antisense RNA strands form an RNA duplex, wherein the sense RNA strand comprises a nucleotide sequence identical to a known target sequence (see Figure 2, page 202 #3, and 3.1 Protocol). Elbashir et al. also teach that the siRNA can be expressed from a plasmid (see Protocol 4.2). Elbashir et al. teach siRNAs as therapeutics and therefore the siRNAs comprise pharmaceutical compositions (see page 213). Elbashir et al. also teach siRNAs comprising pharmaceutically acceptable carriers (e.g. buffers). See page 202 and 203, for example.

WO 0185944 teaches the human ANT1, ANT2, and ANT3 sequences (see SEQ ID NOs: 1, 2, and 3, respectively). It is noted that SEQ ID NOs: 1, 2, and 3 taught by WO 0185944 are all 100% complementary to SEQ ID NOs: 19, 20, and 21, respectively of Applicant's invention. WO 0185944 also teaches nucleic acids that hybridize to ANT

encoding nucleic acids (see page 20 and page 21). WO 0185944 teach that the nucleic acids of their invention are in the form of RNA or DNA and are double-stranded or single-stranded (see page 21). WO 0185944 also explicitly teach antisense or ribozyme oligonucleotides targeted to ANT (see pages 36 and 37). WO 0185944 also teaches ANT-binding molecules that comprise pharmaceutical compositions and pharmaceutically acceptable carriers that are characterized in an injectable form, or a form that can be administered orally, rectally, or topically (see pages 56-59, for example).

Resolving the level of ordinary skill in the pertinent art

The level of ordinary skill in the pertinent art is considered to be high, being a graduate student or post-doctoral fellow in a biological science.

Considering objective evidence present in the application indicating obviousness or nonobviousness

It would have been *prima facie* obvious to devise an iRNA capable of selectively inhibiting the expression of an ANT isoform, characterized in that said iRNA is an RNA duplex using the teachings of either Faure-Vigny et al. or WO 9410320 and following the teachings and motivation of Hammond et al. and Elbashir et al., combined with the teachings of WO 0185944. It would have been *prima facie* obvious to have the iRNA comprised in a vector construct using the teachings and motivation of WO 9410320 and Elbashir et al., for example. It would have been *prima facie* obvious to have the iRNA comprise a pharmaceutical composition using the teachings of either Faure-Vigny et al., Elbashir et al., or WO 0185944.

One of ordinary skill in the art would have been motivated to devise an inhibitory molecule capable of selectively inhibiting the expression of an ANT isoform, for the purpose of decreasing or arresting tumoral cell proliferation as taught by Faure-Vigny et al. One of ordinary skill in the art would have been motivated to substitute the antisense oligonucleotide inhibitor targeted to ANT taught by Faure-Vigny et al. or WO 9410320 with an iRNA since it is obvious to substitute one functional equivalent for another, particularly when they are to be used for the same purpose. See MPEP 2144.06. Furthermore, of ordinary skill in the art would have been motivated to substitute the antisense oligonucleotide inhibitor targeted to ANT taught by Faure-Vigny et al. or WO 9410320 with an iRNA since Hammond et al. taught that RNA interference is superior to antisense.

One of ordinary skill in the art would have been motivated to have the ANT iRNA comprise a pharmaceutical composition because Faure-Vigny et al. teach the desire to design and use antisense oligonucleotides to inhibit ANT2 expression for the purpose of cancer therapy. Additionally, one of ordinary skill in the art would have been motivated to have the ANT iRNA comprise a pharmaceutical composition since Elbashir et al. teach that siRNA duplexes are useful for therapeutic applications. Furthermore, one of ordinary skill in the art would have been motivated to have the ANT iRNA comprise a pharmaceutical composition since WO 0185944 teaches ANT-binding molecules that comprise pharmaceutical compositions and pharmaceutically acceptable carriers.

One of ordinary skill in the art would have expected success at making an iRNA capable of selectively inhibiting the expression of an ANT isoform, characterized in that

said iRNA is an RNA duplex since Elbashir et al. taught how to successfully use and design siRNAs molecules to a known target gene (see Elbashir et al.) and WO 0185944 taught the sequences of several human ANT genes. One of ordinary skill in the art would have expected success at substituting the ANT antisense oligonucleotide inhibitor taught by WO 9410320 with an iRNA since the substitution of one known element for another would have yielded predictable results at the time of the invention. One of ordinary skill in the art would have expected success at making an ANT iRNA that comprises a pharmaceutical composition since Elbashir et al. taught the successful design of such a composition.

Therefore, the instant invention would have been *prima facie* obvious to one of ordinary skill in the art at the time of filing.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terra C. Gibbs whose telephone number is 571-272-0758. The examiner can normally be reached from 9 am - 5 pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James "Doug" Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

March 10, 2009
/Terra Cotta Gibbs/